In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 19-0007V UNPUBLISHED

PAUL CHRISTENSEN.

Petitioner,

٧.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: February 28, 2022

Special Processing Unit (SPU); Findings of Fact; Site of Vaccination; Onset; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Amy A. Senerth, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Adriana Ruth Teitel, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT¹

On January 2, 2019, Paul Christensen filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the "Vaccine Act"). Petitioner alleged that he suffered a shoulder injury related to vaccine administration ("SIRVA") as a result of an influenza ("flu") vaccine administered to his right shoulder on October 19, 2017. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

¹ Because this unpublished fact ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the fact ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

After review of the record and other filings, and for the reasons discussed below, I find that: (1) Petitioner received the vaccine in his right shoulder, and (2) Petitioner's SIRVA likely began within the 48-hour timeframe for the Table claim.

I. Relevant Procedural History

Mr. Christensen filed his petition for compensation along with medical record exhibits on January 2, 2019. (ECF No. 1). After reviewing the records, Respondent filed a status report stating that he would continue to defend the case. (ECF No. 19). Respondent also noted that this case is a companion case to *Christensen v. Sec'y of Health & Human Servs.*, No. 18-1477, in which Respondent was filing a Rule 4(c) Report. *Id.*

On January 27, 2020, Respondent filed his Rule 4(c) Report maintaining that the case was not appropriate for compensation under the terms of the Vaccine Act. Respondent's Report at 1 (ECF No. 20). Respondent referenced Petitioner's companion case, in which he had alleged that he suffered a *left* shoulder injury as a result of a vaccination. That claim was ultimately dismissed, however, for two reasons. *Christensen v. Sec'y of Health & Hum. Servs.*, No. 18-1477V, 2021 WL 2419720, at *7 (Fed. Cl. Spec. Mstr. May 12, 2021). First, I found that Petitioner had not provide preponderant evidence that his shoulder injury began within 48 hours of vaccination. Instead, the medical record evidence demonstrated that Petitioner complained of left shoulder pain months prior to his vaccination while on a two-week road trip. Second, I found that even if Petitioner wanted to proceed with an off-Table shoulder injury claim, his claim would be barred by the Vaccine Act's 36-month statute of limitations. The case was initiated almost five years from even the latest likely onset, and thus, facially untimely.

In the present matter, Respondent argues, Petitioner's claim also fails to meet the criteria for a Table SIRVA claim, for three reasons. First, Respondent maintains the alleged right shoulder situs has not been preponderantly established. Respondent's Report at 4. Second, Respondent argues that the contemporaneous medical records "suggest that [P]etitioner's right shoulder pain did not begin within 48 hours of his October 2017 vaccination." *Id.* Mr. Christensen did not report his shoulder pain until one month post-vaccination, despite his awareness of the Vaccine Program and the SIRVA claim specifically.

Third, Mr. Christensen's November 2017 MRI revealed another condition or abnormality that would explain his symptoms. Respondent argues that the MRI of Petitioner's right shoulder did not reveal evidence of an inflammatory reaction in the bursa, but rather revealed mild supraspinatus tendinopathy without focal tear.

Respondent's Report at 5. But no treating physician associated these MRI findings with vaccination. *Id*.

The parties agreed to brief the factual issues in dispute. I advised the parties that they could present additional evidence on the third issue in dispute, *i.e.*, the November 2017 MRI, but noted that I might be able to rule on this issue with the evidence presented in the record as it currently stands. Petitioner filed his Motion for a Factual Ruling ("Br.") to resolve the factual issues regarding arm of administration and onset. (ECF No. 26). Respondent filed his response ("Opp.") on August 3, 2020. (ECF No. 27). Petitioner filed a reply ("Reply") on August 17, 2020. (ECF. No. 28). The matter is now ripe for adjudication.

II. Issues

The two issues presented for resolution are:

- (1) Whether Petitioner received the vaccination alleged as causal in his right arm. 42 C.F.R. § 100.3(a) XIV.B. (2017) (influenza vaccination), and
- (2) Whether the onset of Petitioner's right shoulder pain occurred within 48 hours after vaccination, as required by the Vaccine Injury Table. 42 C.F.R. §§ 100.3(a) XIV.B. (2017) (influenza vaccination) and 100.3(c)(10).

III. Authority

Pursuant to Vaccine Act § 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act § 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. § 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which

are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). However, the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." § 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Parties' Positions

a. Petitioner's Arguments

Petitioner asserts that he received the flu vaccine to his right shoulder and that his right shoulder pain started within 48 hours of vaccination. Br. at 1, 7-9. The vaccination record he submitted with his petition did not contain a specification as to which arm received the vaccine. Ex. 1 at 1. Petitioner argues, however, that in the later-filed vaccination record from Costco Pharmacy (Ex. 10), (which indicates that Petitioner received the vaccine to his *left* shoulder), the arm of administration was not contemporaneously recorded, and thus the vaccination records are internally inconsistent. Br. at 7. Furthermore, Petitioner argues that because he underwent left shoulder surgery several years prior, he specifically requested that the flu vaccine be administered to his right shoulder. Petitioner also notes that all of his medical records document an injury and treatment to his right shoulder only. Br. at 7-8. And the medical records are supported by his sworn testimony and the testimony of his fact witness. *Id.* at 8.

Regarding the onset issue, Petitioner notes that he reported shoulder pain less than one month after vaccination. But he maintains he felt right shoulder pain *immediately* after vaccination, which worsened over time. The worsening later motivated him to make an appointment directly with his orthopedist. Br. at 8.

b. Respondent's Arguments

Regarding the situs dispute, Respondent notes that Petitioner submitted two versions of his Immunization Consent form. Opp. at 2. The first version (Ex. 1) does not memorialize an anatomical site of administration, while the second (Ex. 10) indicates the flu vaccine was administrated in Petitioner's *left* arm. Respondent argues that Petitioner and his wife have "inferred" that the administration site must have been added to the second version of the form at a later time, and both asserted the record should thus be considered "unreliable." Opp. at 2. But Respondent maintains that the two exhibits are not copies of the same underlying document, but are actually copies of *two different* documents. *Id.* at 3. Respondent also notes that the second vaccination record (Ex. 10) contains a certification of records signed by an employee of Costco. *Id.* As such, Respondent argues that "it is more likely that (1) the first version submitted was the copy given directly to [P]etitioner at the time he received the vaccination and the second version the Administrative copy kept by Costco and (2) that the vaccine administrator circled the site of administration on her copy and neglected to circle it on the patient copy of the form at the time of vaccination." Thus, the second version stands as the truly

"contemporaneous" item of evidence, and more reliably establishes situs than another silent document. *Id.* at 4.

Turning to onset, Respondent argues that Petitioner's contentions of immediate pain are supported only by his own statement but are uncorroborated by any objective evidence. Opp. at 4. Respondent also argues that because Petitioner had a prior pending SIRVA claim, he would reasonably have been expected to seek care sooner, given his awareness of the Program and SIRVA claims. *Id.* at 5. Therefore, Petitioner's SIRVA claim should be denied

V. Finding of Fact

I make the following findings after a complete review of the record to include all medical records, affidavits, Respondent's Rule 4(c) report, the parties' briefing, and any additional evidence filed. Specifically, I observe as follows:

- Mr. Christensen (a 47 year-old software engineer) received a flu vaccine on October 14, 2017, at Costco Pharmacy. Ex. 1 at 1-3. The initial record of vaccination (Ex. 1) does not specify the situs of administration.³ The vaccination record also contains a handwritten note in response to the question "Have you ever had a serious reaction after receiving an immunization?" This question is marked "Yes" with a handwritten note directly above the question stating: "Too high in shoulder → rotator cuff". Ex. 1, p. 1.
- Another copy of the vaccination record was filed as Exhibit 10. On this version of the document, the Site of Injection section has "LA" circled for "left arm." Ex. 10 at 2.⁴
- Mr. Christensen's medical history reveals that he had a prior left shoulder injury dating back to 2013, and that he underwent left shoulder surgery on February 19, 2014. Ex. 6 at 3. The medical records include an April 17, 2014 note drafted by Dr. David Badger, Petitioner's orthopedist, which states that Mr. Christensen "was eventually diagnosed with a rotator cuff tear due to anatomic impingement of down-turn acromion and had beginning of frozen shoulder. Had laparoscopic surgery to repair things. Since then, things are much better. He has been doing PT." Ex. 3 at 21-23.

³ The petition alleges that Petitioner received the vaccination on October 19, 2017. However, in his Motion for a Factual Ruling (ECF No. 20), Petitioner appears to agree and confirm that he received the flu vaccine on October 14, 2017, as set forth in the record of vaccination. Br. at 1.

⁴ Exhibit 10 contains a certification of records by the Records Custodian of Costco.

- On November 9, 2017 (less than one month post-vaccination), Petitioner presented to Dr. Badger at Ortho Washington for complaints of right shoulder pain. Ex. 2 at 12. The record from this visit states "Patient states he got a flu shot 3 weeks ago and has had pain ever since. He has a constant soreness and sharp pain with reaching and lift[ing] weight." *Id.* Mr. Christensen rated his pain at a 3 on a scale from 0 to 10. *Id.* Upon examination, he exhibited tenderness in the subacromial region and limited range of motion due to pain. The Hawkin's and Neer's impingement tests were both positive. *Id.* at 10. The diagnosis is listed as "Impingement syndrome of right shoulder." *Id.*
- On November 10, 2017, Petitioner underwent an MRI of his right shoulder to assess for right shoulder impingement. Ex. 2 at 16. The impression was "[m]ild supraspinatus tendinopathy without a focal tear... [o]therwise normal MR examination of the right shoulder. No labral tear." Id. at 17.
- On November 17, 2017, Mr. Christensen returned to Ortho Washington to review
 the results of his MRI. Ex. 2 at 11. He received a steroid injection to the right
 shoulder and was instructed to reduce his activities for the day, but that he could
 resume activities the following day. *Id.* He was told to follow up to discuss the
 possibility of shoulder surgery if his shoulder pain continued. *Id.*
- On March 27, 2019, Petitioner returned to Dr. Badger complaining of worsening shoulder pain. Ex. 2 at 8. Mr. Christensen reported that the "cortisone steroid injection ... worked for only 3-4 weeks and now worse." *Id.* He was instructed to continue with ice treatment and to elevate his right shoulder when at rest. Mr. Christensen agreed to move forward with shoulder surgery. *Id.*
- Petitioner underwent a pre-operative examination on March 29, 2018, Ex. 2 at 5-6, and underwent right shoulder surgery on April 11, 2018, Ex. 2 at 14-15. The operative note from the surgery states that "[t]he subacromial space was noted to a have a market subacromial bursitis and a thorough bursectomy was performed. This included an acromioplasty and release of coracoacromial ligament." *Id.* at 15.
- At his first post-operative visit on April 13, 2018, Mr. Christensen was noted to be healing well, with no inflammation and no signs of infection. Ex. 2 at 3. He was instructed to continue with activity modification (no lifting, pulling, pushing) and to keep his right shoulder in a sling with continued ice treatment. *Id.* at 4. Physical therapy was prescribed after his second post-operative exam. *Id.* at 2.
- Mr. Christensen began physical therapy on April 23, 2018. See Ex. 3 generally.
 He underwent 25 sessions over an eight (8) week period and was discharged to

a home exercise program on August 20, 2018. *Id.* At the time of discharge, Mr. Christensen was noted to have "made good progress with respect to his strength, ROM, posture, endurance. He has resumed all his typical activities without increase [symptoms] and he is well educated about continued exercises for home." *Id.* at 70.

• Mr. Christensen filed an affidavit stating that he specifically recalled telling the pharmacist who administered the vaccine to him on October 14, 2017, that he "had a prior left shoulder injury caused by the influenza vaccine in 2013 which required surgery. Therefore, on that day I explained to the vaccine administrator and specifically requested the vaccination in my right arm." Ex. 14 at 1, ¶4. His wife's affidavit corroborates this statement. Ex. 15 at 1, ¶3.

A. Arm of Administration

The record as summarized above preponderantly supports the conclusion that Mr. Christensen received the October 14, 2017 flu vaccine to his right shoulder, despite some inconsistencies in the relevant records.

There are two competing situs records to reconcile. The first one does not specify the right shoulder – but it *does* provide a very credible reason for why Petitioner wanted a right-arm vaccination. It is undisputed that Mr. Christensen had a prior left shoulder injury that necessitated surgery, just three years prior. Thus, on the vaccination record itself, Mr. Christensen wrote that he had a prior serious reaction to a flu vaccination, which corroborates his affidavit, and his wife's affidavit, where he explains that he told the pharmacist to inject his right shoulder because of his previous injury. This explanation is reasonable, and supports the conclusion that Petitioner did likely ask that the vaccine be administered in his right arm, despite the silence of this record.

In the second version, the left arm "LA" has been circled to indicate the vaccination was administered to the patient's left arm. To explain why this document differs from the other, Respondent contends that "the vaccine administrator circled the site of administration on her copy and neglected to circle it on the patient copy of the form at the time of administration." Opp. at 3-4. As such, Respondent argues that I should view this second document as the strongest proof of a contemporaneous record.

I agree that some credence should be given to this second document, especially since it has been certified by the pharmacy as a complete record. However, Respondent's explanation for why the two documents differ is somewhat speculative, since there is no evidence in the record to suggest that this is what actually occurred. It could equally be inferred that the vaccine administrator assumed that the vaccine was administered to Petitioner's left shoulder since most individuals are right-handed, and request that a vaccination be administered to the non-dominant arm, and therefore circled left

automatically. Under the circumstances, Petitioner's personal reason for wanting to avoid a left shoulder vaccination is more compelling and better corroborated by the record.

Also favoring Petitioner on the situs question is the fact that all of Mr. Christensen's medical records filed in this case associated with his post-vaccination treatment document an injury to his right shoulder. Indeed, in his very first medical appointment after vaccination less than a month later, the medical provider, Dr. Badger, notes in his report, "Patient states he got a flu shot 3 weeks ago and has had pain ever since." Ex. 2 at 12. And all subsequent reports of pain and injury following vaccination are consistent with an injury to the right shoulder. "[W]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19. Thus, I find that Petitioner has provided preponderant evidence to support his claim that he received the October 14, 2017 flu vaccine to his right shoulder.

B. Onset

To refute Mr. Christensen's claim that his right shoulder pain began within 48-hours, Respondent objects that Petitioner waited until November 9, 2017 (just 26 days after vaccination) to report his shoulder pain. Because there are no objective findings for the presence of shoulder pain in the days immediately following vaccination, Respondent argues that I cannot find in favor of Petitioner. Respondent also argues that because Mr. Christensen had asserted a prior SIRVA claim regarding his left shoulder, he had knowledge of SIRVA claims in general and should have known to seek care on a more "expedited basis."

Neither argument is persuasive. The delay in seeking treatment herein is not notably lengthy, and thus, not inconsistent with what other Program petitioners experience, based on the assumption that their pain is likely transitory. Many SIRVA cases feature medical record notations from physicians recommending that a patient wait a period of time after vaccination to allow time for the shoulder pain to fade before seeking treatment. Subsequent records corroborate the injury and onset, and the Vaccine Act expressly does not obligate claimants to prove onset issues with evidence from within the alleged timeframe in any event. Section 13(b)(2).

In addition, Respondent's belief that Petitioner should have "known" of his claim (and therefore should be penalized for not acting on his injury sooner) does not substantiate a reason to question onset herein. Indeed, the opposite situation could have also been used as a basis to refute Mr. Christensen's claim. Had Petitioner sought treatment immediately after vaccination, Respondent could have just as easily argued that because of Petitioner's knowledge of the Vaccine Program, he only rushed to seek treatment in an effort to meet this Table element.

Another factor that weighs on my finding of the 48-hour onset of right shoulder pain is the absence of any statement or record that places the onset of Mr. Christensen's right shoulder pain *outside* the 48-hour window. While Respondent correctly notes that Dr. Badger's record memorialized a three-week history of arm pain - which if correct would place the onset of right shoulder pain five days after vaccination (see Opp. at 4) - it is clear from that record that Dr. Badger was generalizing the onset period rather than precisely calculating it from a legal standpoint.⁵ Dr. Badger otherwise clearly sets the onset of Petitioner's right shoulder pain as starting on 10/14/2017, and taken as a whole, this is the most reasonable interpretation of his entire statement.

Respondent further argues that Petitioner cannot overcome inconsistencies or discrepancies in the medical records simply by filing affidavits that gainsay or modify what the records set forth. But the Federal Circuit has expressly recognized that witness testimony on issues pertaining to fact matters like symptoms onset *can* be proven through this kind of evidence (even if they must be weighed against the records, which continue to have evidentiary significance). *Kirby*, 997 F.3d at 1383. Respondent has not otherwise identified any other inconsistencies or discrepancies in the medical records. All other references to onset clearly relate Petitioner's right shoulder pain as occurring immediately after vaccination.

Weighing the evidence overall, I find that Petitioner has met his burden, and thus that onset of Petitioner's pain within 48 hours of vaccination.

C. Petitioner's MRI

I will also address Respondent's argument in the Rule 4(c) Report that Petitioner's November 2017 MRI did not reveal evidence of an inflammatory reaction in or around the bursa, a key element of SIRVA as it is described in the Table's Qualification and Aids to Interpretation (Opp. at 1, fn. 1).⁶ I note that in Petitioner's Exhibit 2, page 14-15, the Operative Report from Mr. Christensen's April 11, 2018 arthroscopic and debridement shoulder surgery, the surgeon found that Petitioner's "subacromial space was noted to have marked subacromial bursitis and a thorough bursectomy was performed." The term "bursitis" is defined in Dorland's Medical Dictionary Online as "inflammation of a bursa, occasionally accompanied by a calcific deposit in the underlying tendon; the most

⁵ The entire statement by Dr. Badger states that Mr. Christensen "states he got a flu shot 3 weeks ago and has had pain ever since." Ex. 2 at 12.

⁶ The Qualifications and Aids to Interpretation define "SIRVA" as an unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. See 42 C.F.R. § 100.3 (c)(10) (Updated March 21, 2017) ("QAI").

common site is the subdeltoid bursa."⁷ Thus, although the November 2017 MRI scan may not have detected inflammation in the bursa, it is clear that when Mr. Christensen underwent surgery and his shoulder bursa was inspected, it was found to have "marked bursitis." Therefore, I am very likely to find preponderant evidence of inflammation in the right shoulder bursa to satisfy the SIRVA Qualifications and Aids Interpretation.

VI. Scheduling Order

Given my findings of fact regarding the arm of administration and the onset of Mr. Christensen's right shoulder pain, Respondent should evaluate and provide his current position regarding the merits of Petitioner's case.

Accordingly, Respondent shall file, by no later than <u>Friday</u>, <u>April 1, 2022</u>, an amended Rule 4(c) Report reflecting Respondent's position in light of the above fact-finding.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

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⁷ (https://www.dorlandsonline.com/dorland/definition?id=7315).